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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,963	09/08/2003	Mark W. Kroll	A03P1062US02	4136

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PACESETTER, INC.  
15900 VALLEY VIEW COURT  
SYLMAR, CA 91392-9221

EXAMINER
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MALAMUD, DEBORAH LESLIE

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/657,963	<b>Applicant(s)</b> KROLL ET AL. <span style="float: right;">C</span>	
	<b>Examiner</b> Deborah Malamud	<b>Art Unit</b> 3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-21 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/8/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The examiner acknowledges the amendments received 08 June 2006. Claims 1-21 are pending.

#### ***Double Patenting/Terminal Disclaimer***

2. The terminal disclaimer filed on 08 June 2006 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 08 September 2003 has been reviewed and is accepted. The terminal disclaimer has been recorded.
3. In view of the terminal disclaimer, the provisional rejection of claims 1, 15 and 20 on the grounds of nonstatutory obviousness type double patenting has been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

4. In view of the amendments to the claims, the examiner withdraws the rejection under 35 USC 112, second paragraph, of claims 8 and 18.

#### ***Claim Objections***

5. Claim 21 is objected to because of the following informalities: the claim states "the system of claim 20" in the first line of the claim. This claim lacks antecedent basis, and should be changed to "the device of claim 20." Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Applicant's arguments, see "Remarks," pages 10-12 filed 08 June 2006, with respect to claim 1 have been fully considered and are persuasive. The rejections of these claims under 35 USC 102(e) have been withdrawn.
8. The rejection of claims 15-16 and 18-21 under 35 USC 102(e) is maintained. For a discussion of the claimed elements, please see the previous Office Action.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
9. Claims 1-12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley et al (U.S. 2003/0208241), or alternatively over Bradley et al (U.S. 2003/0208241) in view of Chen et al (U.S. 6,829,504). Bradley discloses (par. 0010) "an implantable cardiac stimulation device having a sensing circuit for sensing electrical signals from the heart of a patient, a pulse generator for generating pacing pulses for delivery to the heart of the patient, and a control unit. The control unit controls the pulse generator to overdrive pace the heart at an overdrive pacing rate with each pulse set to a standard pacing pulse magnitude. The control unit performs capture verification on each overdrive pacing pulse using signals detected by the sensing circuit. If a pulse fails to evoke capture, the pulse generator is controlled to generate a backup pulse

having a pulse magnitude greater than a standard overdrive pulse magnitude for delivery to the heart tissue.” See Figures 2 and 3.

10. Regarding claims 1-2 and 4-5, Bradley discloses the claimed invention but does not disclose expressly a control unit operative to control the preventive overdrive pacing unit and the ATP therapy unit and switch from preventive overdrive pacing to ATP upon detection of a tachycardia. However, (par. 0040) Bradley does disclose classifying sensed events by comparing them to a predefined rate zone limit in order to determine a type of remedial therapy that is needed. Bradley cites as an example ATP as a remedial therapy. Since Bradley’s system delivers ATP as needed when detecting abnormalities in the signal due to loss of capture, the examiner considers it obvious to one of ordinary skill in the art at the time of the invention that Bradley’s system would detect a tachycardia based on loss of capture prior to delivering antitachycardia pacing therapy.

11. In the alternative, Chen discloses (col. 4, lines 44-54; Figure 1) a system and method for preventing atrial tachycardia, comprising the steps of analyzing a cardiac signal to detect an arrhythmia (such as tachycardia) and delivering one or more defibrillation shocks or cardioversion pulses to capture the heart once an arrhythmia is detected. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bradley’s loss of capture detection unit with Chen’s tachycardia detection and antitachycardia pacing unit in order to properly diagnose an arrhythmia such as tachycardia prior to delivery of a therapeutic pulse, thus preventing inappropriate therapy delivery.

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12. Regarding claims 3 and 17, Bradley discloses the claimed invention except for the predetermined threshold of 60%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the predetermined threshold of 60%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

13. Regarding claim 6, the examiner considers the device shown in Figure 1 to represent an implantable cardiac stimulation device. It is inherent in the system that the pacing and detection of events would take place soon after implantation.

14. Regarding claim 7, Bradley discloses (par. 0011) "the standard overdrive pulse magnitude is determined by performing an automatic capture threshold detection search. The threshold detection search may be performed, for example, whenever two consecutive overdrive pulses fail to evoke capture or may be performed periodically." The examiner considers this to be performing the method periodically.

15. Regarding claim 8, the method illustrated in Figure 3 discloses a repetitive treatment. The examiner considers this to be a method that repeats itself in the manner claimed.

16. Regarding claim 9, Bradley discloses (par. 0013) a rate recovery technique, where overdrive rate is reduced following a sequence of overdrive pacing pulses "capture detection is maintained during rate recovery but the pulse magnitude is increased to the HOM [high output mode] voltage. Once the output is increased to HOM, subsequent LOCs are considered to be intrinsic P-waves. When a predetermined number of P-waves are detected, the rate is increased." The examiner considers this to be a preventive overdrive pacing unit that delivers pacing pulses at a predetermined maximum pulse magnitude; the tachycardia detection unit detects tachycardia based upon the LOC of one or more pacing pulses.

17. Regarding claim 10, Bradley discloses (par. 0012) "when a predetermined number of intrinsic beats are detected, the overdrive rate is increased. The overdrive pulse magnitude is maintained at the elevated pulse magnitude for the next two beats and a full capture assessment is performed. If capture is detected, then the pulse magnitude is incrementally reduced over the next two beats. If capture is not detected, the overdrive rate is not increased; rather the pulse amplitude is immediately increased to a high-output mode (HOM) voltage (e.g. 4.5V)." The examiner considers this to be delivering pacing pulses at a pulse magnitude less than a predetermined pulse magnitude; the tachycardia detection unit detects tachycardia based upon loss of capture of a pacing pulse and a subsequent backup pulse delivered at the maximum pulse magnitude.

18. Regarding claim 11, Bradley discloses (par. 0011) "the standard overdrive pulse magnitude is determined by performing an automatic capture threshold detection search." Bradley further discloses "a back-up pulse is issued after every beat that is not captured during the capture threshold assessment. By providing for automatic capture threshold detection searches, the standard pulse magnitude of the overdrive pulses can be kept as low as possible while still ensuring that substantially all overdrive pulses are properly captured such that backup pulses are not often needed." The examiner

considers this to be an automatic stimulation threshold search unit that performs a stimulation threshold search if a pacing pulse is not captured during preventive overdrive pacing but a backup pulse is captured.

19. Regarding claim 12, the examiner considers the cardiac stimulation device of Figure 1 to be delivering preventive overdrive pacing to the atria.

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley et al (U.S. 2003/0208241) in view of Levine et al (U.S. 6,058,328), or over Bradley et al (U.S. 2003/0208241) in view of Chen et al (U.S. 6,829,504) and in further view of Levine et al (U.S. 6,058,328). Bradley and Chen disclose the claimed invention except for a premature atrial contraction (PAC) detection unit, wherein ATP therapy is delivered upon detection of a loss of capture of a backup pulse delivered subsequent to detection of a PAC by the PAC detection unit during preventive overdrive pacing. Levine however discloses (col. 26, lines 14-23) "if atrial pacing is being provided at 70 bpm, and if a premature atrial contraction (PAC) occurs which changes the effective rate to 74 bpm, then the negative hysteresis feature automatically steps in to increase the atrial paced rate (shorten the atrial escape interval) by, e.g., 5%. Such increased atrial rate is maintained for a prescribed number of cardiac cycles (e.g., 32-256) or for a prescribed time (e.g., 1-5 minutes), at which time the paced rate may be gradually decreased to a prescribed rate (e.g., to a value that is 5-1000 lower than the current paced rate), or gradually decreased until an intrinsic P-wave is sensed." Bradley, Chen and Levine all teach systems for, and methods of, administering various treatment strategies to a heart. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bradley's loss of capture detection unit with Chen's tachycardia detection and antitachycardia pacing unit and with Levine's PAC detection

unit in order to prevent premature atrial contraction as a side effect during overdrive pacing and loss of capture detection.

***Allowable Subject Matter***

21. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


***Conclusion***

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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